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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BADR, HAMID R

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,890	<b>Applicant(s)</b> SCHAAP ET AL.	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-118 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Applicants' amendment file 12/11/2009 is acknowledged.

Rejection of claims 6-7, 11, 13-16, 17, 19, 22, 24 and 26 under 35 U.S.C. 112 second paragraph is withdrawn due to the cancellation of claims by Applicants.

New claims 27-118 are being considered on the merits.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 32, 68, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 32, 68 and 96 are indefinite for "and/or". It is not clear what is meant by "and/or". It is not clear what the applicants regard as the invention.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 27-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijl et al. (WO 97/37032; hereinafter R1) in view of Baugh et al. (US 4,970,167; hereinafter R2).

3. R1 discloses a method for the recovery of microbial polyunsaturated fatty acid (PUFA)-containing oil. The oil is recovered from a microbial biomass after pasteurizing the fermentation broth. (Abstract, and Example 19)

4. R1 discloses that the oil is obtained from a microbial biomass. (page 3, paragraph 1).

5. R1 discloses that the process for obtaining the oil of the invention may remove one or more oxidative or oxidation-causing substances that may have been originally present in the biomass. (page 3, paragraph 4). R1 further discloses that the process can involve the formation of a granular particulate form which may render the PUFA less accessible to atmospheric oxygen, thereby reducing the chances of oxidation. (page 3, paragraph 6)

6. Given the disclosure by R1, regarding the effect of oxygen on oxidation of PUFA, it is clear that removal of oxygen by any known process to protect the PUFA would be obvious to an artisan.

7. The deaeration techniques of claims 31, 67, and 95, a-i, are all known techniques in the art. For instance chemical deaeration by sodium sulphite or hydrazine is well known. Gas displacement techniques using nitrogen are well known. Application of vacuum and stirring under vacuum are all known techniques.

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8. R1 discloses that the oil may contain radical inhibitors, radical scavengers or antioxidants (page 3 last paragraph to page 4 line 1).

9. R1 discloses that the polyunsaturated fatty acid can be C18, C20, C22 omega 3 and C18, C20 or C22 omega 6 or a C20 omega 6 PUFA as presently claimed. These PUFAs include arachidonic acid (ARA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) (page 4, paragraph 1). It also contains gamma linolenic acid (GLA) (page 5, lines 30-34).

10. R1 discloses that the anisidine value of the PUFA containing oil is 0.1-2. (page 5, lines 20-21). Example 23 (page 49-50) shows the results of peroxide value and anisidine value of the extracted oils. Peroxide value of the extracted oil is below 12 and anisidine value is below 20 as presently claimed in claim 27.

11. R1 discloses that the PUFA containing oil can originate from any organism which can produce PUFAs including bacteria, yeast, fungi, algae or a mixture thereof. (page 5, lines 1-2). The organisms claimed in claims 83-85 are all disclosed by R1 (page 4-5).

12. R1 discloses the process for the isolation of one or more compounds from the microbial biomass comprising: culturing the microorganisms in a fermentation broth whereby the compound is produced, pasteurizing the fermentation broth or the microbial biomass derived from the broth and extracting, isolating or recovering the compound from the microbial biomass. (page 7, first paragraph).

13. R1 discloses that the fermentation broth can be filtered. (page 8, lines 15-16)

14. R1 discloses that for thermally stable products processing at higher temperatures e.g. 60C-100C may be applied. R1 teaches of pasteurizing the fermentation broth at

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temperatures from 60C to 100C (page 15, line13-15). R1 also discloses various methods for extracting and obtaining the oil including solvent extraction using hexane (page 31, paragraph 2 and page 29, step i).

15. While R1 discloses that the process can involve the formation of a granular particulate form which may render the PUFA less accessible to atmospheric oxygen, thereby reducing the chances of oxidation, R1 is silent regarding deaerating an aqueous liquid comprising microbial cells as presently claimed.

16. R2 discloses a post fermentation degassing technique. (Abstract). R2 discloses a sequential fermentation and degassing of fermentation broths. (Col. 2, lines 34-40).

17. R2 discloses means for culturing or fermentation of microbial cells (Col. 6, Fermentation). R2 also discloses means for degassing (degassification ) of a fermentation broth (Col. 10, Degassification) including degassing nozzles (Col. 3, lines 15-40). R2 discloses that the vapor space in the degassification chamber can be maintained at atmospheric, sub-atmospheric or super atmospheric pressure. Given that the chamber can be operated at sub-atmospheric pressures (vacuum operated), the deaerator of claim 23-24 will be obvious to those of skill in the art. The vacuum pressures can also be optimized so that the concentration of dissolved oxygen can be lowered to levels including those concentrations as presently claimed in claims 13-14. Given that sub-atmospheric pressures as well as nozzles in the degassing chamber are disclosed by R2, the vacuum, degassing pump or nozzle of claim 25 will be also obvious to those of skill in the art.

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18. R2 discloses that the degassed fermentation broth can be pasteurized (Col. 4, lines 35-39). Given that pasteurization can be carried out after the degassing process, the limitation of claim 92, i.e. heating the cells after deaeration, would be obvious to those of skill in the art.

19. Given the disclosure by R2 regarding the operation of the degassing chamber under vacuum, the limitations of claim 100 which are equivalent to -200 mbar to -400 mbar vacuum are operational vacuums and can be optimized by those of skill in the art. Since under standard pressure and temperature (1 atm pressure and 25°C) the solubility of oxygen in water is about 8 ppm, lowering the pressure will cause a decrease in the concentration of dissolved oxygen. Therefore, an artisan would be able to reduce the pressure to a level where the solubility of oxygen is decreased to a point, obviously less than 10 ppm, so that PUFA will no longer be oxidized at an accelerated rate.

20. Since R1 discloses the sensitivity of polyunsaturated fatty acids to oxidation by atmospheric oxygen and remedies the problem through certain means, it is obvious that those of skill in the art are motivated to use other means of deaerating the fermentation broth, as disclosed by R2) to protect the sensitive polyunsaturated fatty acids.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to grow PUFA containing cells in a fermentation process as taught by R1 and exclude oxygen from the fermentation broth as taught by R2, or other techniques known in the art, to protect the highly unsaturated fatty acids from oxidation. One would do so to obtain microbial oils which are nutritionally and organoleptically of high quality. Absent any evidence to contrary and based on the combined teachings of

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the cited references, there would be a reasonable expectation of success in preparing microbial oils containing PUFA of high quality.

### ***Response to Arguments***

Applicants' arguments have been reviewed thoroughly. They are deemed persuasive for the following reasons.

1. Applicants argue that R1 does not disclose an oil comprising at least 35% of a desired C20 or C22 PUFA and that the highest PUFA disclosed by R1 is 32.6% of DHA; Additionally the oxidative stability of the DHA oil is not described.

a. R1 discloses the production of DHA containing oil with specific reference to the protection of the oil from oxidative damage. The 32.6% concentration reported by R1 is the result of only one working example. The level of DHA can be manipulated through selection of microbial strains as well as fermentation media and conditions all of which are well within the skill of the art. On the other hand the presently claimed 35% PUFA and the disclosed content of 32.6% are so close that the presently claimed invention is an obvious version of the disclosure by R1.

2. Applicants argue that R2 does not even talk about PUFA.

a. R2 is a secondary reference which is used for its teachings on mechanical deaeration of fermentation broth comprising cells, which is presently claimed.

Additionally R2 discloses the heating of cells after the deaeration process which is another feature of the presently claimed invention.

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However, note that while R2 does not disclose all the features of the present claimed invention, R2 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

3. Applicants argue that the presently claimed invention provides high PUFA content together with high oxidative stability.

a. R1 also provides oils of high PUFA and high oxidative stability. The anisidine value disclosed by R1 is 0.1-2 which is much lower than 20 as presently claimed.

Therefore the oil, disclosed by R1, is highly stable.

4. Applicants argue that Table 1 shows that by applying deaeration, the quality of the oil was improved significantly as expressed by lower values for anisidine value for the oil prepared according to the claimed invention.

a. Applicants are dealing with highly unsaturated oils which are well known in the art to undergo oxidation in the presence of oxygen. It is obvious that excluding oxygen through deaeration will result in much less oxidized (low anisidine value) oils. Therefore, the results are expected results.

5. Applicants argue that i) there is no teaching deaerating and lowering the dissolved oxygen content in the aqueous liquid improves the oxidative stability of the oil; ii) there is no teaching or suggestion that an oil having the combination of the claimed

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high PUFA content and a low anisidine value can be obtained and iii) the combination of or R1 and R2 does not result in the claimed invention.

a. sections i) and ii) are known phenomena in the art; meaning that protecting highly unsaturated oils from oxygen will result in better quality oils (as evidenced by anisidine value or peroxide value). For section iii) it should be realized that the invention is basically disclosed by R1, the primary reference, however, R2 is only a teaching reference which discloses methods of deaerating a fermentation broth.

6. Applicants argue that the idea of deaeration would not be necessarily thought to be an advantageous strategy because this might result in the cells dying, or at the very least their ability to produce PUFA and other valuable compounds might be compromised.

a. It should be realized that the gas displacement technique as presented at page 7 of the instant specification, starts the deaeration process toward the end of the fermentation. The biomass should have been formed by that time and deaeration, for instance by gas displacement using nitrogen, will not affect the cell mass critically. What it does, it will lower dissolved oxygen in the broth and the subsequent cake (filtered cells) and in doing so it will protect the PUFA which will be extracted next.

### ***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner  
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